UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/622,163	07/17/2003	Khalid Iqbal	MERZ 35	2196

25666 7590 06/14/2007

THE FIRM OF HUESCHEN AND SAGE
SEVENTH FLOOR, KALAMAZOO BUILDING
107 WEST MICHIGAN AVENUE
KALAMAZOO, MI 49007

EXAMINER	
CHONG, YONG SOO	

ART UNIT	PAPER NUMBER
1617	

MAIL DATE	DELIVERY MODE
06/14/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/622,163	IQBAL ET AL.	
	Examiner	Art Unit	
	Yong S. Chong	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 April 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-16* is/are pending in the application.

4a) Of the above claim(s) *6 and 7* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5 and 8-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *1/31/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Application

This Office Action is in response to applicant's response filed on 4/2/2007. Applicant's election **with** traverse of the restriction requirement in the reply is acknowledged. The traversal is on the ground(s) that a chemist would not find the instant invention to involve structurally distinct inventions. This is not found persuasive because a multitude of patentably distinct structures based on ring size and substituents comprise the compounds of formula I. Examiner notes that while the species requirement of a single disclosed compound of formula I is maintained, the species requirement of a single disclosed disorder is withdrawn from record. The requirement is still deemed proper and is therefore made FINAL. Claim(s) 1-16 are pending.

Claim(s) 6-7 are withdrawn from further consideration as being drawn to a non-elected species. Claim(s) 1-5, 8-16 are examined herein insofar as they read on the elected invention and species.

Claim Objections

Claim(s) 9 is objected to because of the following informalities: the term "Down's syndrom" should be spelled "Down's syndrome."

Claim(s) 16 is objected to because of the following informalities: the term "mamantine" should be spelled "memantine."

Examiner will assume the correct spelling of these terms for examination purposes. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-5, 8-16 are rejected under 35 U.S.C. 112, first paragraph, because the specification does not reasonably provide enablement for *preventing* a disorder resulting from hyperphosphorylation of microtubule protein tau. The specification does not enable any person skilled in the art to which it pertains to practice the invention commensurate in scope with these claims.

The instant specification fails to provide information that would allow the skilled artisan to fully practice the instant invention without undue experimentation. Attention is directed to *In re Wands*, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApls 1986) at 547, the court recited eight factors: (1) the nature of the invention; (2) the state of the prior art; (3) the breadth of the claims; (4) the amount of direction or guidance presented; (5) the predictability or unpredictability of the art; (6) the relative skill of those in the art; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary.

(1) The Nature of the Invention: The rejected claims are drawn to an invention which pertains to a method of treating and preventing a disorder resulting from hyperphosphorylation of microtubule protein tau.

(2) State of the Prior Art: The state of the art regarding treating a disorder resulting from hyperphosphorylation of microtubule protein tau, such as Parkinson's disease and Alzheimer's disease, is relatively high, however the state of the art for the prevention of a disorder resulting from hyperphosphorylation of microtubule protein tau is non-existent.

(3) Breadth of Claims: The complex nature of the subject matter of this invention is greatly exacerbated by the breadth of the claims. The claims encompass the prevention, inhibition, and treatment of a disorder resulting from hyperphosphorylation of microtubule protein tau.

(4) Guidance of the Specification: The guidance of the specification as to the prevention of a disorder resulting from hyperphosphorylation of microtubule protein tau is completely lacking. The specification discloses preventing the onset of a disorder resulting from hyperphosphorylation of microtubule protein tau. However, the specification fails to mention how one is able to determine whether the onset of a disorder resulting from hyperphosphorylation of microtubule protein tau in a subject would have occurred in the absence of treatment, thus being unable to confirm that prevention has indeed taken place. Moreover, the specification fails to mention the complete prevention or cessation of a disorder resulting from hyperphosphorylation of microtubule protein tau once the onset of preclinically evident stage is determined.

(5) The Predictability or Unpredictability of the Art: The invention is directed to a method of treating, inhibiting, and preventing a disorder resulting from hyperphosphorylation of microtubule protein tau. The specification does not disclose

how one of ordinary skill in the art at the time of the invention would be able to prevent a disorder resulting from hyperphosphorylation of microtubule protein tau, nor does the prior art reveal any type of prevention associated with a disorder resulting from hyperphosphorylation of microtubule protein tau.

(6) The Relative Skill of those in the Art: One of ordinary skill in the art does not know how to prevent a disorder resulting from hyperphosphorylation of microtubule protein tau. Moreover, one is unable to determine whether a subject will ever develop a disorder resulting from hyperphosphorylation of microtubule protein tau should this subject be administered a compound of formula I.

(7) Working Examples: The specification does not give any data for the prevention of a disorder resulting from hyperphosphorylation of microtubule protein tau.

(8) The Quantity of Experimentation Necessary: The specification fails to provide support for the prevention of a disorder resulting from hyperphosphorylation of microtubule protein tau. Nor does it provide information to practice the claimed invention, absent undue experimentation. Genetech, 108 F. 3d at 1366 states that "a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion" and "patent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable."

Claims 1, 3, 8-11 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for compounds of formula I, does not reasonably provide enablement for any aminocyclohexane or aminoalkylcyclohexane. The

specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

The instant specification fails to provide information that would allow the skilled artisan to fully practice the instant invention without undue experimentation. Attention is directed to *In re Wands*, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApls 1986) at 547, the court recited eight factors: (1) the nature of the invention; (2) the state of the prior art; (3) the breadth of the claims; (4) the amount of direction or guidance presented; (5) the predictability or unpredictability of the art; (6) the relative skill of those in the art; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary.

(1) The Nature of the Invention: The rejected claims are drawn to an invention, which pertains to a method of prevention and treatment of a disorder resulting from hyperphosphorylation of microtubule protein tau by administering any aminocyclohexane or aminoalkylcyclohexane.

(2) State of the Prior Art: The state of the art regarding aminocyclohexane or aminoalkylcyclohexane is high, but the state of the art regarding the prevention and treatment of a disorder resulting from hyperphosphorylation of microtubule protein tau by administering any aminocyclohexane or aminoalkylcyclohexane is relatively low.

(3) Breadth of Claims: The complex nature of the subject matter of this invention is greatly exacerbated by the breadth of the claims. The claims encompass any aminocyclohexane or aminoalkylcyclohexane.

(4) Guidance of the Specification: The guidance of the specification is limited to aminocyclohexanes and aminoalkylcyclohexanes of formula I.

(5) The Predictability or Unpredictability of the Art: The invention is directed to any possible compound that can be structurally classified as an aminocyclohexane or aminoalkylcyclohexane.

(6) The Relative Skill of those in the Art: One of ordinary skill in the art does not know how to prevent and treat of a disorder resulting from hyperphosphorylation of microtubule protein tau by administering any aminocyclohexane or aminoalkylcyclohexane

(7) Working Examples: The specification is again limited to just aminocyclohexanes and aminoalkylcyclohexanes of formula I.

(8) The Quantity of Experimentation Necessary: The specification fails to provide support for the method of prevention and treatment of a disorder resulting from hyperphosphorylation of microtubule protein tau by administering any aminocyclohexane or aminoalkylcyclohexane. Nor does it provide information to practice the claimed invention, absent undue experimentation. Genetech, 108 F. 3d at 1366 states that "a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion" and "patent protection is granted in return

for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable."

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-5, 8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It not clear what exactly is "a state, disorder, or condition resulting from hyperphosphorylation of microtubule protein tau?"

Claims 1-5, 8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It not clear what exactly is "a clinical symptom or parameter of a state, disorder, or condition resulting from hyperphosphorylation of microtubule protein tau?"

Claim(s) 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, claim(s) 1 recites the limitation "the disease." There is insufficient antecedent basis for this limitation in the claims.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim(s) 1-5, 8-16 are rejected under 35 U.S.C. 102(b) as being anticipated by Shapiro (US Patent 5,668,117).

Shapiro discloses treating neurological diseases, such as Parkinson's disease, with a composition comprising memantine at a dosage of 10 to 400 mg daily (example 1). Examiner notes that the limitations regarding the symptoms and etiology are considered preamble and will be given little patentable weight. Furthermore, the mechanism of action of the instant claims is inherent when the patient population, active agent, and the dosage are the same.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yong S. Chong whose telephone number is (571)-272-8513. The examiner can normally be reached on M-F, 9-6.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, SREENI PADMANABHAN can be reached on (571)-272-0629. The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

YSC

SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER